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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,373	05/16/2001	Robert P. Kimberly	UAB-14202/22	5348

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09/04/2002

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EXAMINER

SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/744,373

Applicant(s)

KIMBERLY, ROBERT P.

Examiner

Sally A Sakelaris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

*Election/Lack of Unity*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention(as represented by the groups listed below) to which the claims must be restricted.

Group I, claims 1-21, and 26-35 are drawn to methods of determining susceptibility to a disease through the identification of the genotype, as relayed through polynucleotide analysis and kits containing reagents.

Group II, claims 22-25, 34 and 35 are drawn to a method of determining susceptibility to a disease through the identification of the phenotype, as relayed through amino acid and polypeptide analysis and kits containing reagents.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It is noted that each of the present claims has been presented in improper Markush format, as distinct methods are improperly joined in the claims. With respect to the methods of Groups I and II, each one consists of analysis using an unique nucleic acid or polypeptide respectively, each differing in its structural and functional properties. Additionally, the method claims of Groups I and II are distinct from the other in that both the nucleic acid of group I and

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the polypeptide of Group II, being analysed in the method, comprise a distinct structure and as a whole each biomolecule is functionally distinct over each other. Each method has a different special technical feature. As the claimed methods use both analysis with polynucleotides and polypeptides, they do not share a special technical feature and the distinct methods may not properly be presented in the alternative. Accordingly, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed by the claims, and the claims will be searched only as they read upon the elected invention from the methods of Groups I and II that require different analyses using either polynucleotides or polypeptides.

For example, if group I is elected, only the polynucleotide encompassing claim language will be examined. ie., the kits of claims 34 and 35 will include only the reagents necessary and relevant to the analysis of genotyping nucleic acids.

Further, the claimed methods of Groups I and II have different objectives, require different process steps and require the use of different reagents. The method of Group I requires the steps of identifying the genotype of a cell through nucleic acid analysis. The method of Group II requires the steps of identifying the phenotype of a cell through polypeptide analysis. While Group I is directed to a method utilizing nucleic acids as a reagent, composed of phosphodiester linked nucleotides, Group II is directed to a method utilizing polypeptides as a reagent , composed of peptide bond linked amino acids.

The nucleic acid and polypeptide require different method steps to accommodate their variant physical characteristics. In addition to differences in objectives, effects, and method steps, it is again noted that the method claims of the present Groups are not directed to the

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detection or identification of molecules having the same or common special technical feature, for the reasons discussed above.

3. Because these inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, examination of these inventions lacking the same special technical feature would pose a serious burden on the examiner and therefore the lack of unity requirement and subsequent election of desired Group for examination purposes as indicated is proper.

4. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris



8/28/2002



CARLA J. MYERS  
PRIMARY EXAMINER